FAQ

Date: 7/8/2004
Subject: USP 797, Pharmaceutical Compounding-Sterile Preparations

Q What is the USP 797 and how does it impact Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Accreditation?

A The USP 797 provides the mandatory requirements for compounding sterile preparations (CSPs) and protecting patients from receiving erroneous or inadvertent contaminated medications. The USP 797 addresses a number of issues, such as quality assurance; microbial contamination risk levels; competency and responsibility of the individuals preparing CSPs; patient or caregiver training requirements; infection control; storage; and environmental design, quality, and control of the CSPs preparation areas. The USP 797 went into effect in January 2004 and the JCAHO began assessing compliance in July 2004. The JCAHO expects all accredited organizations to comply with USP 797, and the affected JCAHO standards are –

- National Patient Safety Goal #7, Hand Hygiene
- Performance Improvement (PI.1.10, 2.10, 2.20, 3.10)
- Leadership (LD.1.30, 3.80, 4.10, and 4.70)
- Human Resources (HR.2.30 and 3.10)
- Infection Control (IC.1.10 and 4.10)
- Medication Management (MM.4.20, 4.30, 4.40, 4.80, 5.10, and 6.10)
- Patient Care, Treatment, and Services (PC.6.10)
- Environment of Care (EC) (EC.6.10, 7.10, 8.10, and 9.10)

Q What should EC Managers do to help Pharmacy personnel meet the USP 797 requirements and the corresponding JCAHO EC standards?

A First, the Pharmacy must identify all CSP preparation, storage, and other medicine dispensing locations (e.g., main and satellite pharmacies, operating rooms, immunization clinics, and patient care areas) and assign an appropriate risk level (low, medium, high) for each location. Risk level is based on potential for microbiological, chemical, or physical contamination. Once all locations are identified and risk levels are determined, Safety, Facilities, and Medical Equipment Mangers must work with the Pharmacy to complete the following actions –

- Assess the CSP preparation areas for compliance with USP 797 environmental design requirements
- Conduct air quality testing and environmental monitoring of CSP preparation areas
- Conduct temperature testing of CSP storage areas
- Calibrate and maintain automated compounding equipment used to prepare CSPs
- Develop an action plan for all identified environmental deficiencies and assign specific, realistic timeframes for completion. The action plan must be approved by leadership.

A table that lists the affected EC standards, describes the USP requirements for each risk category, and states the JCAHO's timeframes for compliance follows.

References:
U.S. Pharmacopeia. USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. The United States Pharmacopeial Convention, Inc., 2003.
Rich, D.S. "Legal and JCAHO Implications." 20 June 2004. American Society of Health-System Pharmacists. Online. http://www.ashp.org/SterileCpd/).

EC Standard	USP Requirements	Target Timeframe for Compliance
EC.6.10 The hospital manages medical equipment risks		
Automated Compounding Devices for Parenteral Nutrition Compounding	• Written policies and procedures that address calibration, routine maintenance, and personnel training • Equipment is calibrated • Routine maintenance is performed	**July 2005**
Temperature Testing of Drug Storage Areas	• Daily monitoring of controlled temperature storage areas in the pharmacy (e.g., refrigerators, freezers, and incubators) • Where used: - Calibrated thermometers must be periodically calibrated - Continuous temperature recording devices must be checked for proper function daily	**July 2005**
EC.7.10 The hospital manages utility risks		
Utility Systems Testing	• Certification of Laminar Airflow workbenches (LAFW), barrier isolates, and biological safety cabinets (BSCs) every 6 months and whenever they are relocated • Certification of buffer zone and ante room every six months and whenever renovations occur	**January 2005**
EC.8.10 The hospital establishes and maintains an appropriate environment		
Environmental Design	**Critical Areas** are locations where CSPs are directly exposed to air in the physical environment. • Air quality is ISO Class 5[1] (e.g., LAFW, barrier isolates, BSCs) • Airflow is through high-efficiency particulate air (HEPA) filters and unidirectional or columnar	• Interim measures by **January 2005** • Renovation plan by **July 2004** • Completion by **January 2008**
	Buffer Zone or Clean Rooms are controlled areas where LAFW, barrier isolates, or BSCs are installed. • Air quality is ISO Class 8[2] • Air pressure is positive relative to adjacent pharmacy areas • Air conditioning and humidity controls are in place • Ceilings, walls, floor, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, non-shedding (stainless steel or molded plastic) and resistant to damage caused by sanitizing agents • Inlaid ceiling tiles are be treated with a polymer to render them impervious and hydrophobic, and they are caulked around their perimeters to seal them to their support frames • Exterior lens surfaces on ceiling lighting fixtures are smooth, mounted flush, and sealed • Junctures between ceiling and walls are coved or caulked • Walls are panels locked together and sealed or epoxy-coated gypsum board • Overhangs, ledges, windowsills are avoided • Furniture, equipment, and supplies limited to what is required for tasks to be performed • Floors are overlaid with wide sheet vinyl flooring with heat-welded seams and coving to the sidewall • All wall and floor penetrations are sealed • No sinks or floor drains	
	Ante Room precedes the buffer zones and is used for storage and providing a clean area for donning personal protective equipment.	
	Low Risk: • Demarcation line or barrier to between zone and ante room • Sinks equipped with hot and cold running water and hands-free faucets • Personnel must be able to access buffer zone without the use of their hands **High Risk:** • All low/medium risk requirements except the ante room is physically isolated from the buffer zone	
EC.9.20 The hospital analyzes identified environment issues and develops recommendations for resolving them		
Environmental Bacterial Monitoring	**Low Risk:** • Monthly **High Risk:** • Weekly	**January 2006**

[1] ISO Class 5 is equivalent to 3520 particles of 0.5 µm and larger per m^3 or 100 particles per ft^3
[2] ISO Class 8 is equivalent to 3,520,000 particles of 0.5 µm and larger per m^3 or 100,000 particles per ft^3